

1. Claims 14-26 are under consideration.
2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 14-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the . . . claimed subject matter", *Vas-Cath, Inc. V. Mahurkar*, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed inventions.

The instant claims encompass a method that uses a "compound that depletes or inhibits B lymphocytes" wherein said compound also has the functional effects recited in the claims. However, the specification only provides written description of antiCD20 antibodies such as rituximab which bind human CD20 for use in the claimed method. The claims encompass a vast collection of structurally unrelated molecules which have the functional properties recited in the claims and wherein the identity of such molecules is unknown and unpredictable (aka antisense reagents, small organic molecules, fusion proteins, etc.). The claims encompass use of antibodies which bind nonhuman CD20 from any mammalian species wherein the identity of CD20 from species other than human or murine does not appear to have been known in the art and is unpredictable. With the exception of antihuman or antimurine CD20 antibodies, the skilled artisan cannot envision the detailed structure of the encompassed antiCD20 antibodies and reagents, and therefore conception is not achieved until reduction to practice has

occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See *The Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In *University of California v. Eli Lilly and Co.*, 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, *id.* at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", *Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd.*, 18 U.S.P.Q.2d 016 (Fed. Cir. 1991). Attention is also directed to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein is stated: "The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA." See *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 14-24,26 are rejected under 35 U.S.C. 102(b) as being anticipated by Weng et al. (aka Wen-Kai Weng et al.) as evidenced by Anderson et al. (US 5,736,137). Weng et al. disclose treatment of follicular lymphoma patients with antiCD20 antibody rituximab and a therapeutic vaccination with tumor idotype (see entire reference). The antiCD20 antibody rituximab is inherently a chimeric monoclonal antibody obtained by genetic engineering (see Anderson et al., columns 6-30 wherein C2B8 is rituximab). Weng et al. disclose that said method stimulates (aka amplifies) a CTL T cell response (aka the CTL are excited, see entire reference). Rituximab inherently has the binding specificity and functional properties recited in the claims (see Anderson et al., columns 6-30 wherein C2B8 is rituximab). The idotype vaccine is administered prior to antiCD20 antibody (see entire reference).

6. Claims 14-24,26 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson et al. as evidenced by Anderson et al. (US 5,736,137). Wilson et al. disclose treatment of MCL lymphoma patients with antiCD20 antibody rituximab (aka EPOCH-R wherein the R is rituximab) and a therapeutic vaccination with tumor idotype (see entire reference). The antiCD20 antibody rituximab is a chimeric monoclonal antibody obtained by genetic engineering (see Anderson et al., columns 6-30 wherein C2B8 is rituximab). Wilson et al. disclose that said method stimulates (aka amplifies) T cell responses including tumor cell lysis (aka the CTL are excited, see entire reference). Rituximab inherently has the binding specificity and functional properties recited in the claims (see Anderson et al., columns 6-30 wherein C2B8 is rituximab). The idotype vaccine is administered after antiCD20 antibody (see entire reference). Wilson et al. teach that B cell depletion can enhance cellular responses (see second sentence).

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 14-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. and Anderson et al. (US 5,736,137) in view of Andrieu et al. (US 2004/00009194).

Wilson et al. disclose treatment of MCL lymphoma patients with antiCD20 antibody rituximab (aka EPOCH-R wherein the R is rituximab) and a therapeutic vaccination with tumor idotype (see entire reference). The antiCD20 antibody rituximab is a chimeric monoclonal antibody obtained by genetic engineering (see Anderson et al., columns 6-30 wherein C2B8 is rituximab). Wilson et al. disclose that said method stimulates T cell responses including tumor cell lysis (aka the CTL are excited, see entire reference). Rituximab has the binding specificity and functional properties recited in the claims (see Anderson et al., columns 6-30 wherein C2B8 is rituximab). The idotype vaccine is administered after antiCD20 antibody (see entire reference). Wilson et al. teach that B cell depletion can enhance cellular responses (see second sentence) and provide evidence in humans that the treated patients have enhanced cellular responses (see

second page). Wilson et al. do not teach that the patients received the vaccine of claim 14. Andrieu et al. teach the vaccine of claim 14 (see [0062] and claims 1-18). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Wilson et al. teach that B cell depletion can enhance cellular responses (see second sentence) and provide evidence in humans that treated patients have enhanced cellular responses whilst Andrieu et al. teach the vaccine of claim 14. One of ordinary skill in the art would have been motivated to do the aforementioned because Wilson et al. teach that B cell depletion can enhance cellular responses (see second sentence) and provide evidence in humans that treated patients have enhanced cellular responses. The vaccine of Andrieu et al. works via cellular immune responses (see [0062]). Furthermore, in KSR Int'l Co. v. Teleflex Inc., 550 U.S. m, 2007 WL 1237837, at "13 (2007) it was stated that **"if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill"**.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Ron Schwadron, Ph.D./
Primary Examiner, Art Unit 1644